



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/268,437	03/12/1999	YING DING	UOC/134A	8426

26875 7590 03/28/2005
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/268,437

Applicant(s)

DING ET AL.

Examiner

Gailene R. Gabel

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11 and 12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 1/7/05 is acknowledged and has been entered. Claims 1 and 11 have been amended. Claims 6-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-9, 11, and 12 are pending. Claims 1-5, 11, and 12 are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague in reciting, "adapted to receive a sample", because it is unclear how the "cell" is modified to perform its intended function. For example, 1) does the cell have a channel connected thereto adapted to receive a sample. See also claim 11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558) for reason of record.

Henkens et al. disclose a simultaneous electrochemical assay device (biosensor array device) comprising a cell (circuit board) for holding a sample, having a plurality of plurality of working electrodes and reference, i.e. auxiliary, electrodes. Each of the working electrodes is adjacent, i.e. linked or attached to, an analyte binding area which has an analyte binding substrate and separate from other analyte binding areas by a distance (surface area). Henkens et al. teach that whether in an array of working electrodes or a single working electrode, the biosensor may optionally include one, i.e. common, or more reference counter electrodes (see column 6, lines 32-38 and Figure 14). Analyte binding substrates (bioreporter molecules) comprise of different analyte specific proteins such as antigens, antibodies, and enzymes (reductases, peroxidases, phosphatases). See column 4, line 41 to column 6, line 38 and column 19, line 58 to column 20, line 56. The plurality of working electrodes quantitatively measure

Art Unit: 1641

enzymatic reaction product. See column 17, line 51 to column 18, line 63 and column 41, lines 31-38. The device does not include a means to mix the sample in the cell.

5. Claim 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081).

Cozzette et al. disclose a simultaneous electrochemical assay device (amperometric base sensor) fabricated on a substantially planar silicon substrate comprising a unit cell for holding a sample, having a plurality of working (catalytic) electrodes with identical geometry and area, and having analyte binding areas (biolayer) and enzyme incorporated thereto, wherein the working electrodes quantitatively measure enzymatic reaction product (see column 3, lines 12-28, column 13, lines 22-53, column 19, lines 23-45, column 16, lines 28-42, and column 22, lines 18-36). The unit cell may be repeated in a geometric array several hundred times on a single silicon wafer. Each working electrode is surrounded by an auxiliary (combined counter and reference) electrode. Each of the working electrodes are adjacent to permselective silane layer having immobilized thereon, the analyte binding areas which are localized on the electrode portions of the unit cell and separated from adjacent analyte binding areas by a distance (see column 25, line 35 to column 26, line 4). The working electrodes on analyte binding areas are overlain and aligned with analyte specific proteins such as antigens and antibodies (biolayer and bioactive molecules) (see column 22). Cozzette et al. specifically teach that a plurality of electrodes may be present in a biosensor for the simultaneous measurement of different analytes (see

Art Unit: 1641

column 25 and Figure 4). The device does not include a means to mix the sample in the cell.

Response to Arguments

6. Applicant's arguments filed 1/7/05 have been fully considered but they are not persuasive.

A) Applicant requests that Henkens et al. be withdrawn as a reference because the application has a filing date of April 14, 2000 and since it is only based on a continuation-in-part application and not the provisional application which has a filing date of March 18, 1997. Applicant contends that the disclosure of Henkens is not the same and therefore, the rejection is inappropriate.

In response, while the disclosure of Henkens '558 which is a CIP application may include subject matter that is new to the disclosure of ASN 09/044, 206, but the subject matter and limitations relied upon in Henkens '558 to reject the instant claims is disclosed in parent application 09/044,206 and provisional application 60/040,949, then the benefit of priority is given to the patented child application for purposes of prior art rejection for the subject matter at issue. In this case, ASN 09/044,206 appears to disclose the subject matter relied upon to reject the instant claimed invention.

Contrary to Applicant's argument, Henkens et al. at column 6, lines 33-38 appear to teach biosensor having an array of working electrodes, having one, i.e. common, counter electrode, as recited in the rejected claims.

B) Applicant argues that Cozzette et al. does not anticipate the claimed invention because it teaches a method of forming individual assay devices on a silicon chip. Applicant contends that Cozzette et al. do not teach a simultaneous electrochemical assay device and that it merely teaches a structure that must be modified to be further incorporated into an electrochemical assay device. According to Applicant, the actual finished state of the device taught by Cozzette can only be used to test one analyte.

In response, while Cozzette et al. disclose methods of manufacturing microfabricated sensing devices, the subject matter relied upon to reject the claimed invention appears to teach electrochemical devices used in electrochemical assay methods such as recited in the rejected claims. Contrary to Applicant's argument that the electrochemical device of Cozzette cannot test multiple analytes simultaneously, the teaching of Cozzette et al. at column 58, lines 38-48 and Figure 4 appears to teach a plurality of [indicator] electrodes in the biosensor device for the simultaneous measurement of different analytes, i.e. ionic species such as Na, K, Cl, etc.

7. For reasons aforementioned, no claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1641

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 16641
March 21, 2005

86


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/21/05